

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM**

Civil Action No. MDL 2326

**Action Pending in the: Southern District of
West Virginia**

PRODUCTS LIABILITY LITIGATION

Charleston Division

**PLAINTIFFS' NOTICE OF ISSUANCE OF SUBPOENA TO ADVANCE MEDICAL
TECHNOLOGIES ASSOCIATION ("ADVAMED")**

PLEASE TAKE NOTICE that testimony will be taken by video deposition upon oral examination, pursuant to Federal Rule of Civil Procedure 45, pursuant to the Subpoena attached hereto, and that Plaintiffs intend to serve said Subpoena on Advance Medical Technologies Association ("AdvaMed") on January 23, 2013, or as soon thereafter said service may be effectuated.

Date: January 23, 2013

Respectfully submitted,

/s/ Aimee H. Wagstaff

Aimee Wagstaff

ANDRUS HOOD & WAGSTAFF, PC

Colo Bar. No. 36819; CA Bar No. 278480

1999 Broadway, Suite 4150

Denver, Colorado 80202

Telephone: (720) 208-9414

Aimee.wagstaff@ahw-law.com

CERTIFICATE OF SERVICE

I declare under penalty of perjury that, on January 23, 2013, on behalf of the Plaintiffs' Steering Committee, *In Re: Boston Scientific Corp.*, Pelvic Repair Systems Liability Litigation, MDL No. 2326, I served the foregoing *Notice of Subpoena* by Electronic Mail upon:

Jon Strongman, Esq.
Shook, Hardy & Bacon, LLP
2555 Grand Blvd.
Kansas City Missouri 6410
jstrongman@shb.com

/s/ Aimee H. Wagstaff
Aimee Wagstaff
ANDRUS HOOD & WAGSTAFF, PC
Colo Bar. No. 36819; CA Bar No. 278480
1999 Broadway, Suite 4150
Denver, Colorado 80202
Telephone: (720) 208-9414
Aimee.wagstaff@ahw-law.com

EXHIBIT A

1. Pursuant to Federal Rule of Civil Procedure 45, testimony will be taking by video deposition upon oral examination before a person authorized by the laws of the District of Columbia to administer oaths on **FEBRUARY 13, 2013, at 10:00 a.m.**, at the office of Ashcraft & Gerel LLP located at 2000 L Street, N.W., Washington, D.C. 20036, as set forth in the attached Subpoena. Said deponent appearing on behalf of Advance Medical Technology Association (“AdvaMed”) shall be the person/representative with the most knowledge concerning the membership, activities and/or participation of the transvaginal surgical mesh manufacturers within AdvaMed’s organization, including but not limited to the following:

- a. Acell;
- b. American Medical Systems, Inc. (“AMS”) and/or American Medical Systems Holdings, Inc. (“AMS Holdings”);
- c. Bio-vascular, Inc.;
- d. Boston Scientific Corporation;
- e. Brennen Medical, Inc.;
- f. C.R. Bard, Inc. (“Bard”);
- g. Caldera Medical, Inc.;
- h. Coloplast A/S;
- i. Cook Biotech, Inc.;
- j. Cousin Biotech S.A.R.L.;
- k. Cryolife, Inc.;
- l. Endo Pharmaceuticals, Inc., Endo Health Solutions, Inc. (f/k/a Endo Pharmaceutical Holdings, Inc.);
- m. Ethicon, Inc., Ethicon Women’s Health and Urology, Gynecare, and/or Johnson & Johnson, Inc. (“Ethicon”);
- n. GFE Medixintechnik GmbH;
- o. Herniamesh SRL;

- p. Kensey Nash Corporation;
- q. Life Cell Corporation;
- r. Macropore Biosurgery Inc.;
- s. MedVenture Technology Corporation;
- t. Mpathy Medical Devices, Ltd.;
- u. Neomedic International;
- v. Organogenesis, Inc.;
- w. Osteobiologics, Inc.;
- x. Pegasus Biologics, Inc.;
- y. Promethean Surgical Devices, Inc.;
- z. Proxy Biomedical, Ltd.;
- aa. Proxy Biomedical, Inc.;
- bb. RTI Biologics, Inc.;
- cc. Shelhigh, Inc.;
- dd. Sofradim Production SAS (“Sofradim”);
- ee. Synovis Surgical Innovations;
- ff. TEI Bioscience, Inc.;
- gg. Tepha, Inc.;
- hh. Covidien (Tissues Science Laboratories, PLC) (“TSL”);
- ii. W.L. Gore & Associates, Inc.;
- jj. Xylos Corporation;
- kk. Gyne Ideas, Ltd., and
- ll. Prosurg, Inc.

2. That said deponent shall be the person/representative with the most knowledge concerning AdvaMed and its members’ activities and communications relating to the safety and efficacy of transvaginal surgical mesh products, and any communications and submissions to the

United States Food and Drug Administration (“FDA”) relating to transvaginal surgical mesh products, including, but not limited to the following:

- a. Preparation, attendance, or presentation of the Docket Submission to the September 8 and 2011 Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee entitled “Safety and Effectiveness of Transvaginal Surgical Mesh Used for Repair Of Pelvic Organ Prolapse;”
- b. Preparation, attendance, and/or presentation by AdvaMed during the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee;
- c. Preparation, attendance, and/or presentation to any domestic and/or foreign governmental body, representative, or agency;
- d. Preparation, attendance, and/or presentation to any legislator, healthcare provider, medical societies, and/or medical technology conferences;
- e. The industry working group known as the “Transvaginal Mesh Industry Working Group,” including scientific literature and reports reviewed;
- f. Involvement of the media relations organization known as “newsPRO;” and
- g. Any communications and submissions made in anticipation to or in response to, and otherwise relating to, the FDA’s “Section 522 Order” issued in January 2012.

3. That said deponent shall be the person/representative that possesses the following documents, tangible things and electronically stored information within possession, custody and control of the witness pursuant to Fed. R. Civ. P. 26 and Rule 45, as set out below.

A. Definitions

The following definitions are applicable to the request for documents to be produced by Advanced Medical Technology Association (“AdvaMed”) as described herein:

1. The terms “documents” or “electronically-stored information” is ascribed to the meaning set forth in Federal Rule of Civil Procedure 34.1(a)(1)(A).
2. The term “or” means and/or, and the term “and” means and/or.
3. The term “you” means the answering party, Advanced Medical Technology Associations (“AdvaMed”).
4. The term “transvaginal surgical mesh products” means all transvaginal surgical

mesh products used for the treatment of pelvic organ prolapse (“POP”) or stress urinary incontinence (“SUI”).

B. Categories of Documents to be Produced

1. All documents concerning the risks, safety, or efficacy of transvaginal surgical mesh products from 2005 to present, including but not limited to the AdvaMed members and/or manufactures identified *supra* at 1-2.

2. All documents concerning the preparation, presentation or attendance on behalf of AdvaMed or its transvaginal surgical mesh product manufacturer members during the Obstetrics and Gynecology Devices Panel of the United States Food and Drug Administration (“FDA”)’s Medical Devices Advisory Committee held on September 8 and 9, 2011, including but not limited to:

- a. Preparation of the Docket Submission to the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel entitled “Safety and Effectiveness of Transvaginal Surgical Mesh Used For Repair Of Pelvic Organ Prolapse;”
- b. Scientific literature discussing the risks, safety and efficacy of transvaginal surgical mesh products;
- c. Premarket clinical and preclinical studies, and postmarket studies evaluating the safety and effectiveness of transvaginal surgical mesh for the treatment of pelvic organ prolapse or stress urinary incontinence;
- d. The classification of the transvaginal surgical mesh products to Class III (Premarket Approval);
- e. Discussion, analysis of, or reference to FDA’s 510(k) decision or submission process, including science reports; and
- f. Premarket and postmarket review protocols, policies, or procedures.

3. All documents concerning the industry working group formed by AdvaMed from 2005 to present, known as the “Transvaginal Mesh Industry Working Group,” including but not limited to the following concerning transvaginal surgical mesh products:

- a. Preparation of the Docket Submission to the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel entitled “Safety and Effectiveness of Transvaginal Surgical Mesh Used For Repair Of Pelvic Organ Prolapse;”
- b. Scientific literature discussing the risks, safety and efficacy of transvaginal surgical mesh products;

- c. Premarket clinical and preclinical studies, and postmarket studies evaluating the safety and effectiveness of transvaginal surgical mesh for the treatment of pelvic organ prolapse or stress urinary incontinence;
 - d. The declassification of the transvaginal surgical mesh products to Class III (Premarket Approval);
 - e. Discussion, analysis of, or reference to FDA's 510(k) decision or submission process, including science reports;
 - f. Premarket and postmarket review protocols, policies, or procedures;
 - g. Meeting minutes, notes or memoranda from organizational group meetings; and
 - h. Any communications and submissions made in anticipation to or in response to otherwise relating to the FDA's "Section 522 Order" issued in January 2012.
4. All documents by AdvaMed or its member companies' relating to communications and submissions with or to legislators, regulators, domestic and foreign governmental bodies, health care providers, medical societies and patient organizations, concerning the risks, safety, efficacy, or the FDA 510(k) decision or submission process, of transvaginal surgical mesh products from 2005 to present.
5. All documents or communications concerning the risks, safety and efficacy of transvaginal surgical mesh products presented by AdvaMed at any medical technology conference from 2005 to present.
6. All documents communicated by AdvaMed or its transvaginal surgical mesh product manufacturer members with the medical relations organization "newsPRo," concerning the risks, safety, efficacy, or the FDA 510(k) decision or submission process of the transvaginal surgical mesh products from 2005 to present.
7. All documents relating to the FDA's "Section 522 Order" issued in January 2012.

Respectfully submitted,

Dated: January 23, 2013

/s/ Aimee H. Wagstaff

Aimee Wagstaff

ANDRUS HOOD & WAGSTAFF, PC

Colo Bar. No. 36819; CA Bar No. 278480

1999 Broadway, Suite 4150

Denver, Colorado 80202

Telephone: (720) 208-9414

Aimee.wagstaff@ahw-law.com

/s/ Clayton A. Clark

Clark Love & Hutson, GP

440 Louisiana Street, Street 1600

Houston, Texas 77002

(713) 757 - 1400

CClark@triallawfirm.com

*Co-Lead Counsel in for Plaintiffs in MDL
No. 2326*